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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,077	02/03/2006	Frank Theobald	5121002053	2323

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EXAMINER

WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
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1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,077	Applicant(s) THEOBALD ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3 - 13 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 - 6, 8 - 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed September 29, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Specification

1. The disclosure was objected to because of the use of the trade name ORMOCER® that was not capitalized and accompanied by generic terminology. This objection is MAINTAINED.

Applicant argues that this term is widely equated with the term “inorganic-organic composites” and it is not being used as a trademarks as it is not referred to in all capital letters or accompanied by either TM or ®.

These arguments are not persuasive. ORMOCER® is a live trademark (registration number 2831241) and Applicant does not the authority to use the same term as a generic term merely by not capitalizing it and not using the appropriate symbol.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3 – 6 and 8 – 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 28, 2008 and those set forth below.

Applicant traverses this rejection on the same grounds as the objection to the specification for the use of ormocer in lowercase and without accompanying generic terminology.

As discussed in greater detail above, this argument is not persuasive and the rejection of the claims is maintained.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 4 – 6 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. (US 4,710,191) in view of Amberg-Schwab et al. (J Sol-Gel Sci and Tech Jan 2003). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 28, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Kwiatek does not disclose or suggest the use inorganic-organic copolymers as a suitable material for the outer backing layer and the combination with Amberg does not remedy this deficiency. Amberg is directed towards the use of inorganic-organic polymer as migration barriers against liquid and volatile compounds in the context of products useful in the food packaging or pharmaceutical packaging industry, which represents a teaching away from transdermal devices as claimed or taught in Kwiatek. Also the covering film of the

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instant invention maintains both a barrier effect and elastic properties, a combination that is not taught or suggested by the combination of Kwiatek and Amberg. Amberg is directed towards packaged products, suggesting a teaching away by providing a barrier effect with inelastic properties.

These arguments are not found persuasive. Amberg-Schwab is silent as to the use of these materials in transdermal systems and the mere absence of a teaching of their use in a particular application does not constitute teaching away from the use for that particular application. Amberg-Schwab is reasonably pertinent to the particular problem with which the applicant was concerned and can be relied upon as a basis for rejection of the claimed invention. In this case, the important properties backing layer of Kwiatek et al. in the transdermal device are it is impermeable to the layers in contact with it, such as the active ingredient, and to prevent seepage of the active ingredient from the device. It is the barrier properties of the materials which are discussed in Amberg-Schwab and thus Amberg-Schwab teaches a different material from those disclosed by Kwiatek with the same properties as the materials suitable for use in a backing layer. Thus, the ORMOVER® material of Amberg-Schwab is functionally equivalent to the backing layer materials disclosed by Kwiatek et al.

The barrier and elastic properties of the material are inherent to the materials being used. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a

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new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The use of an inorganic-organic polymer as the backing layer in the transdermal device of Kwiatek must result in a system which has both barrier and elastic properties as the components of the instant claims and the combined device taught by Kwiatek et al. and Amberg-Schwab et al. are the same, namely a device comprising a peelable protective layer, a reservoir or matrix layer with active compound and a covering film comprised of at least one supporting layer of at least one organic polymer and at least one layer composed of an ormocer. Again, the silence of reference(s) to a particular property does not constitute teachings away from the claimed invention.

8. Claims 1, 3 and 9 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. and Amberg-Schwab et al. further in view of Osborne et al. (US 5,004,610). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 28, 2008 and those set forth below.

Applicant traverses this rejection on the grounds discussed above as the added claims ultimately depend from claim 1.

As discussed above, these arguments are not persuasive and therefore this rejection is maintained.

The newly added claims contain a new limitation of the ormocer later is applied to the supporting layer such that it is adjacent to the active compound containing layer. As

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shown in figure 1 of Osborne et al., the impermeable backing (2) is adjacent to the active compound containing layer or reservoir (3).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW